What is claimed is:

1. A biological fluid constituent sampling and concentration measurement device, said device comprising:

(a) at least one skin-piercing member comprising a biological fluid access opening;

(b) an electrochemical cell for measuring the concentration of analyte within the biological fluid, wherein the cell comprises at least one porous electrode; and

(c) a constituent transfer medium comprising a hydrophilic material in fluid communication with the at least one skin-piercing member and with the at least one porous electrode.

2. The device of claim 1 wherein the hydrophilic material comprises a gel matrix.

3. The device of claim 2 wherein the gel matrix comprises a natural gel.

4. The device of claim 3 wherein the natural gel is selected from the group comprising agarose, gelatin, mucopolysaccharide, starch and the like.

5. The device of claim 2 wherein the gel matrix comprises a synthetic gel.

6. The device of claim 5 wherein the synthetic gel comprises a neutral water-soluble polymer.

7. The device of claim 2 wherein the synthetic gel comprises a polymer.

8. The device of claim 7 wherein the polymer is selected from the group consisting of polyvinyl pyrrolidone, polyethylene glycol, polyacrylic acid, polyvinyl alcohol, polyacrylamide, and copolymers thereof.

9. The device of claim 1 wherein the electrochemical cell comprises two spaced-apart electrodes defining a reaction chamber, wherein at least one electrode is porous.

10. The device of claim 9 wherein the distance between the electrodes is from about 50 to 1000 Å.

11. The device of claim 10 wherein the distance between the electrodes is from about 100 to 500 Å.

12. The device of claim 11 further comprising at least one reagent material for chemically reacting with at least one biological fluid constituent, the at least one reagent material located on a surface of at least one electrode facing the reaction chamber, wherein the at least one reagent is selected based on the at least one constituent targeted for measurement.

13. The device of claim 9 wherein both electrodes are porous.

14. The device of claim 13 further comprising a housing having at least one vent hole for venting air from within the electrochemical cell.

15. The device of claim 9 wherein a first porous electrode comprises pores having diameters in the range from about 25 μm to 200 μm.

16. The device of claim 15 wherein the diameters are in the range from 50 to 150 μm.

17. The device of claim 16 wherein the diameters are in the range from about 100 to 150 μm.

18. The device of claim 9 wherein a second porous electrode comprises pores having diameters in the range from about 0.1 to 50 μm.

19. The device of claim 18 wherein the diameters are in the range from about 0.1 to 10 μm.

20. The device of claim 1 wherein the biological fluid is interstitial fluid and the analyte is glucose.

21. A biological fluid constituent sampling and concentration measurement device, said device comprising:

(a) an array of micro-needles, each micro-needle having an access opening;

(b) a layer of hyrdophilic gel material over the array;

(c) a first layer of conductive material over the layer of hydrophilic gel material, wherein the first layer of conductive material is porous and further wherein the access openings, the layer of hydrophilic gel material and the first layer of conductive material provide a constituent transfer pathway; and

(d) a second layer of conductive material, wherein the first layer of conductive material and the second layer of conductive material are spaced-apart, wherein biological fluid present at the access opening is caused to be transferred to the space between the first and second layers of conductive material.

22. The device of claim 21 further comprising a layer of insulating material over the second layer of conductive material.

23. The device of claim 21 wherein the array of micro-needles comprises an insulating material.

24. The device of claim 21 further comprising a layer of at least one reagent material between the first and second layers of conductive material, wherein at least one biological fluid

constituent present in the space between the first and second layers of conductive material chemically reacts with the at least one reagent material.

25. The device of claim 24 wherein the layer of at least one reagent material contacts either the first layer of conductive material, the second layer of conductive material or both.

26. The device of claim 21 wherein the second layer of conductive material is porous.

27. The device of claim 26 further comprising an insulating layer over the second layer of porous conductive material, wherein the insulating layer has a venting hole there through.

28. The device of claim 21 wherein the biological fluid being accessed is interstitial fluid and the constituent being measured is glucose.

29. The device of claim 28 wherein the reagent comprises a glucose oxidizing enzyme and a mediator.

30. The device of claim 29 wherein the enzyme is selected from a group consisting of glucose oxidase and glucose dehydrogenase.

31. The device of claim 30 wherein the mediator is ferricyanide.

32. The device of claim 21 wherein the micro-needles of the array of micro-needles have varying lengths.

33. A system for sampling biological fluid constituents from the skin of a patient and measuring at least one target constituent within the sampled biological fluid constituents, the system comprising:

(a) at least one device according to claim 1; and

(b) a control means in electrical communication with the at least one device, the control means comprising:

(1) means for sending an electrical input signal to the device and for receiving an electrical output signal from the device, and

(2) a software algorithm which automatically calculates and determines the concentration of the target analyte in the accessed biological fluid upon receipt of the electrical output signal.

34. The system of claim 33 further comprising a display means in electrical communication with the control means for displaying information in the form of electrical signals received from the control means related to the sampling of the at least one biological fluid constituents and the measuring of the at least one target constituent.

35. The system of claim 33 further comprising a housing wherein the control means is located within the housing and the device is mounted to the housing.

36. The system of claim 34 wherein the device is mounted to the housing by means of a lock-and-release mechanism.

37. The system of claim 35 further comprising user input buttons on the housing for providing user input to the control unit.

38. The system of claim 35 further comprising a display means on the housing for displaying information from the control means.

39. The system of claim 35 wherein the housing has a hand-held configuration.

40. A method for accessing a biological fluid within the skin of a patient, and for sampling constituents therein and determining the concentration of at least one target analyte contained therein, the method comprising the steps of:

providing at least one micro-needle comprising an open distal end and a channel therethrough;

inserting the at least one micro-needle into the skin to a selected depth;

absorbing into the micro-needle channel constituents present within biological fluid at the open distal end; and

diffusing the absorbed constituents to and through a conductive material into a measurement chamber.

41. The method of claim 40 further comprising the steps of:

causing the sampled constituents to chemically react with a selected reagent within the measurement chamber;

providing a first signal to the measurement chamber; and

receiving a second signal from the measurement chamber, wherein the second electrical signal is representative of the concentration of the target analyte in the accessed biological fluid.

42. The method according to claim 40 further comprising the steps of:

exerting a capillary force on the sampled biological fluid present in the measurement chamber; and

transferring the sampled constituents through a second conductive material.

43. The method according to claim 42 further comprising the step of venting air from the measurement chamber.

44. The method of 41 further comprising the step of deriving the concentration level of the at least one target analyte in the patient's blood from the second signal.

45. The method of claim 44 further comprising the step of displaying a numerical value representative of the concentration of the at least one target analyte in the patient's blood.

46. The method according to claim 45 wherein the step of deriving comprises using a software algorithm.

47. The method according to claim 41 wherein the accessed biological fluid is interstitial fluid and the at least one target analyte is glucose.

48. A method for sampling biological fluid constituents within the skin of a patient and for measuring the concentration of one or more target analytes contained therein, the method comprising the steps of:

providing a system comprising a first constituent sampling and analyte concentration measurement device according to claim 1 and a control unit, wherein the device is operatively coupled to the control unit;

operatively applying the first device to the patient's skin wherein the system samples the patient's biological fluid constituents and measures the concentration of the one or more target analytes therein;

removing the first device from the patient's skin;

removing the first device from the control unit;

operatively coupling a second constituent sampling and analyte concentration measurement device according to claim 1 to the control unit; and

repeating the above steps until the desired number of samplings and measurements has been performed.

49. A kit for sampling biological fluid constituents from the skin of a patient and for measuring the concentration of at least one analyte within the sampled biological fluid constituents, the kit comprising:

at least one device according to claim 1; and

a control means according to claim 33.

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50 49
51. The kit of claim 50 wherein the control means is reusable.

51 50
52. The kit of claim 51 wherein the at least one device comprises two or more reagent materials for testing two or more targeted analytes.

52
53. A kit for sampling biological fluid constituents from the skin of a patient and for measuring the concentration of at least one analyte within the sampled biological fluid constituents, the kit comprising a plurality of devices according to claim 1.

53 52
54. The kit of claim 53 wherein the plurality of devices is disposable.